UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Guidant Litagation

Civil No. 05-1141 (DWF/AJB)

ALL CASES

AMENDED ORDER FOR THE PRESERVATION OF EVIDENCE

Pursuant to the court's duty to supervise pretrial proceedings in this case, including discovery, and pursuant to the court's inherent power, the court hereby orders, effective immediately, that Guidant Corporation, Cardiac Pacemakers, Inc., Guidant Sales Corporation, their officers, agents, employees and attorneys (collectively, "Guidant") and plaintiffs and their attorneys:

Device Preservation

A. Shall not destroy, dispose of, alter, remove, or destructively test any physical evidence relevant to the plaintiffs' alleged defects in the Ventak Prizm AVT Model 1900; Vitality AVT Models A135 and A155; Contak Renewal 3 AVT Models M150, M155, M157, M159, Contak Renewal 4 AVT M170, M175, M177, and M179; Ventak Prizm 2DR Model 1861 (manufactured on or before April 16, 2002); Contak Renewal Model H135 and Contak Renewal 2 Model H155 cardiac resynchronization therapy defibrillators manufactured on or before August 26, 2004; and Contak Renewal 3 and 4, Contak Renewal 3 AVT and Contak Renewal

4 AVT, and Renewal RF Models H170, H173, H175, H177, H179, H190, H195, H197, H199, M150, M155, M157, M159, M170, M175, M177, M179, H230, H235, and H239. If the parties conduct any testing or analysis of such devices, they shall ensure that electronic data concerning patient-specific information and system diagnostics stored in the devices is preserved. It is not necessary to download software code from each individual device because it is being maintained electronically.

When devices identified in the preceding paragraph are surgically removed, Guidant representatives who are present shall perform or use their best efforts to request that physicians perform a "Save to Disk" function before removal and shall ensure that data saved to a computer disk or other memory device is preserved intact pending further order of this court or another court with jurisdiction. In the event that explanted devices are placed in the custody of Guidant or its agents, defendants shall ensure that the devices are saved in a manner that preserves their electronic integrity and the integrity of any data and/or program code contained in the devices, shall label the device with identifying patient information and the date and location of the explant procedure, and shall store the devices at room temperature away from strong magnetic fields.

This order shall not prohibit:

(1) Conducting electrical tests of returned devices after the preservation of electronic data defined in paragraph (A). Where there is visual evidence of polyimide degradation, X-rays or photographs shall be taken in the case of Prizm 2 DR 1861, Contak Renewal and Contak Renewal 2. In the ordinary course, such testing should not alter or destroy evidence.

(2) Erasing memory to perform electrical testing where the memory to be erased is already otherwise preserved.

(3) Destructive testing specifically requested by FDA or otherwise necessary to Guidant's CAPA, provided that Guidant maintains a written, and where applicable, photographic record of such testing.

(4) Testing required to comply with regulations of foreign governments, provided that Guidant maintains a written, and where applicable, photographic record of such testing.

(5) Destructive testing of Ventak Prizm 2 DR 1861, manufactured prior to April 16, 2002, pursuant to Guidant's obligations under 21 CFR § 820.198 where the device does not manifest arcing in the header as described in Guidant's press release of June 17, 2005, but is alleged to have performed out of specifications in the field or in the lab. Guidant shall maintain a written and, where applicable, a photographic record of any such testing.

(6) Destructive testing of Contak Renewal or Contak Renewal 2, manufactured prior to August 26, 2004, pursuant to Guidant's obligations under 21 CFR § 820.198 where the device does not manifest arcing in the header as described in Guidant's press release of June 17, 2005, but is alleged to have performed out of specifications in the field or in the lab. Guidant shall maintain a written and, where applicable, a photographic record of any such testing.

(7) Destructive testing of Ventak Prizm AVT, Vitality AVT, Contak Renwal AVT, Contak Renwal 3 AVT or Contak Renewal 4 AVT pursuant to Guidant's obligations under 21 CFR § 820.198 where the device does not manifest latching as described in Guidant's press release of June 17, 2005, but is alleged to have performed out of specifications in the field or in the lab. Guidant shall maintain a written and, where applicable, a photographic record of any such testing. Further, if an AVT device demonstrates latching upon return, Guidant may issue a reset command to the device to pull it out of the loop and enable interrogation with programmer hardware, enable the printing reports and generation of patient data disks which will contain details of the final episodes. (The court expects that with this approach, no data will be lost, only the loop will be terminated. If the devices are left in a latched state, the batteries will deplete in a few months.)

(8) Destructive testing of a Contak Renewal 3 or Contak Renewal 4 or Contak Renewal 3 AVT or Contak Renewal 4 AVT or Renewal RF pursuant to Guidant's obligations under 21 CFR § 820.198 where the device does manifest a

Microswitch issue as described in Guidant's press release of June 23, 2005 in that Guidant shall open the case halves of the pulse generator to access the component to obtain an x-ray image of the component, and obtain a photograph, measure the switch and probe the switch to assess its performance; destructive testing of the switch itself. This order also shall not prohibit destructive testing of a Contak Renewal 3 or Contak Renewal 4 or Contak Renewal 3 AVT or Contak Renewal 4 AVT or Renewal RF where the device does not manifest a Microswitch issue as described in Guidant's press release of June 23, 2005, but is alleged to have performed out of specifications in the field or in the lab. Guidant shall maintain a written and, where applicable, photographic record of any such testing.

(9) Return of a device listed in Paragraph A to a patient or patient representative pursuant to patient request.

B. Guidant may re-institute its ordinary device retention policy for devices not specified in Paragraph A or otherwise subject to litigation.

C. Any patient who is a named plaintiff in any action subject to this order (including plaintiffs in any action who have agreed to coordinate discovery with this action) and who keeps an explanted device shall:

(1) Immediately provide Guidant with the model number and serial number for tracking purposes;

(2) Provide Guidant an opportunity to perform a "Save to Disk" and "Hex Dump" download at the time of explant or within 5 days after the patient comes into possession of the device;

(3) Refrain from destroying, disposing of, altering, removing or destructively testing any such device, pending further order of this court for testing of explanted devices;

(4) Provide Guidant with an opportunity to have a designated representative visually inspect the device;

(5) Refrain from allowing their expert to perform any analysis or testing of a device prior to giving Guidant an opportunity to conduct a physical inspection of the device and an opportunity to be present during any electrical or destructive analysis or testing, and shall record any such testing by video or audio.

If a plaintiff who is a named plaintiff in an action subject to this order is already in possession of an explanted device, the patient shall comply with the requirements of this Paragraph C and its subparts immediately above.

Document Preservation

D. Shall not purge data, delete data, erase disks, tapes or electronic files of any kind, erase memory, or otherwise alter, change, modify or destroy information (including any meta data) stored in or by computer (regardless of

whether that information is created and/or stored before or after the entry of this order) relevant to plaintiffs' claims of alleged defects in the device models specified in Paragraph A. Plaintiffs shall have the same obligation for information relevant to defendants' defenses. This Order shall not prohibit the following actions:

(1) E-mail

(a) Reuse of incremental and/or daily tapes as part of tape rotation where full back-up tapes are being retained for all e-mail servers worldwide which are cumulative of changes over time.

(b) Deletion of e-mail going forward by individuals whose accounts are journaled, which means that every e-mail sent or received for these people is captured and placed in a secure vault.

(c) Deletion of past e-mail by individuals whose accounts have been archived to a secure vault for discovery purposes, provided that such archiving must include not only such individuals' in-box but also any other folders or archives of saved e-mail received or sent by such individuals.

(d) Application of normal tape retention of e-mail server tapes after the archiving has been completed, if the archiving and journaling process includes all individuals whose e-mails are encompassed by the e-mail server tapes.

(2) Project Netware Share Files: Re-use of incremental and/or daily tapes as part of tape rotation where full back-up tapes for the project

network file shares are being retained. The R&D file shares in St. Paul have been locked-down for change.

(3) Network Home Directories: Re-use of incremental and/or daily tapes as part of the Company's tape rotation where full back-up tapes for the Network Home directories (U:\ drives) are being retained.

(4) Application(s) / System(s)

(a) Re-use of incremental and/or daily tapes where full back-up tapes for the applicable applications / systems are being retained.

(b) Changing applications as required to conduct business (primarily adding functionality) where the application team has been contacted and is managing a log of all such changes to the application and is maintaining copies of source and object code for all versions of the applications.

E. Shall preserve software and programs written regarding the devices, including but not limited to software and programs to obtain, manage, read, or manipulate data from patient data disks.

F. Shall preserve information contained on or representing patient data disks and on laptop computers (including those used by doctor/field

representatives) and information exchanged on VPN networks relating to the devices listed in Paragraph A.

G. Shall not shred, change, modify, alter, remove, destroy, sanitize, or otherwise dispose of documents, photographs, videotapes, or any other type of documentary evidence of information relevant to the plaintiffs' claims of alleged defects in the device models specified in Paragraph A. Plaintiffs shall have the same obligation for information relevant to defendants' defenses.

H. May destroy or otherwise alter specified documents due to routine policy or programs after providing specific and detailed written notice to the other parties, including information as to the routine policy or program at issue and identification of the documents or categories thereof, if no other such party notifies defendants in writing, through counsel, of its objections within thirty days. If an objection is raised, the parties may raise the issue with this court or any other court with jurisdiction and shall preserve the documents in question pending resolution by the court.

I. May, without leave of court, agree in writing that certain documents or categories of documents or evidence need not be preserved in accordance with this Order. If such agreement is reached, such agreement is effective upon signing without further order of court.

J. Each party shall bear its own costs for complying with this order.

Date: September 16, 2005

s/ Arthur J. Boylan
ARTHUR J. BOYLAN
U.S. Magistrate Judge

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